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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,297	03/31/2006	Cindy Castado	VB60452	9309

23347 7590 04/07/2009

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
04/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/574,297	CASTADO ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,23-36,53-66,69,70 and 72* is/are pending in the application.

4a) Of the above claim(s) *1-10,12,13,23-28,31,54-56,58 and 60-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 30, 33-36, 53, 57, and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/26/2008 and 3/31/2006* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 12-17-08. Claims 1-11, and 36 are amended. Claims 14-22 and 37-52 have been cancelled. Claim 72 is a new claim.

Election/Restrictions

2. Applicant's election with traverse of Group IV and the specific combination of the polypeptide with the amino acid of SEQ ID NO:34, FHA and pertussis toxin is acknowledged. The traversal is on the ground(s) that Wang et al is published without a sequence listing. This is not found persuasive because The technical feature of Group I, an immunogenic composition comprising a polypeptide comprising an amino acid sequence which has at least 85% identity to SEQ ID NO: 34, over the entire length of SEQ ID NO: 34, or an immunogenic fragment thereof, and a pharmaceutically acceptable excipient. The technical feature is unpatentable over Wang et al WO200277183-A2 Date October 3, 2002. Wang et al teach a polypeptide comprising an amino acid sequence which has at least 85% identity to SEQ ID NO: 34 (see Claim 25; SEQ ID NO 50795).

Furthermore the sequence is listed in an attachment as "STIC RESULTS".

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-13, 23-36, 53-66, 69-70, and 72 are pending. Claims 1-10, 12-13, 23-28, 31, 34-35, 56-64, 69-70, and 72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn nonelected inventions, there being no allowable generic or linking claim. The election of species of Group C of Phase species (claims 53-57) on pg. 10 of the previous restriction on 11/17/2008 has been withdrawn from consideration. Claims 11, 29-30, 32-33, 36, 53-54 and 65-66 are currently under examination.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

4. The drawings in this application have been accepted. No further action by Applicant is required.

Specification

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

6. The information disclosure statement filed on 8/26/2008 and 3/31/2006 has been considered. Initialed copies are enclosed.

Claim Rejections - 35 USC § 112, Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 65-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The rejected claims are drawn to vaccine compositions capable of stimulating a protective immune response in an animal *to Bordetella spp.* wherein said vaccine

compositions are drawn to a broad genus polypeptides that are at least 70% identical to SEQ ID NO:34,.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of *vaccine* compositions comprising a polypeptide that is at least 70% identical, Applicant must adequately describe the antigenic determinants (immunoepitopes) that elicit a protective immune response directed against a given *Bordetella* species not just those determinants that would elicit an immune response to the polypeptide itself since given polypeptide can be immunogenic but not induce an protective immune response directed against a given *Bordetella* species.

The specification, however, does not disclose distinguishing and identifying features of a representative number of members of the genus of immunogenic compositions to which the claims are drawn, such as a correlation between the structure of the immunoepitope and its recited function (to elicit a protective immune response directed against a given *Bordetella* species), so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of immunogenic compositions. Moreover, the specification fails to disclose which amino acid residues are essential to the function of the immunoepitope or which amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent, or by which other amino acids the essential amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent. Therefore, since the specification fails to adequately describe at least a substantial number of members of the genus of immunoepitopes to which the claims are based; the specification fails to adequately describe at least a substantial number of members of the claimed genus of immunogenic compositions capable of stimulating a protective immune response in an

animal *to* a given *Bordetella* species.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description'' Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described

distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Greenspan et al. (*Nature Biotechnology* **7**: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows that the immunoepitopes that can elicit a protective immune response to a given pathogen can only be identified empirically. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of immunoepitopes, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of vaccine compositions capable of stimulating an immune response in an animal *to* a given *Bordetella* species (as opposed to the polypeptide) said composition comprising a polypeptide that is at least 70% identical to SEQ ID NO:34. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of immunoepitopes (antigenic determinants) is not deemed representative of the genus of vaccine compositions to which the claims refer and therefore the claimed invention is not properly disclosed.

Enablement

8. Claims 65-66 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contain subject matter, which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabled for any vaccine comprising an immunogenic composition comprising a) a Bordetella autotransporter protein consisting of polypeptide sharing at least 70% identity with SEQ ID NO:34 or antigenic fragment thereof; b) a Bordetella adhesin consisting of FHA or antigenic fragment thereof; and c) a Bordetella toxin/invasion or antigens involved in toxin/invasion secretion consisting of pertussis toxin or antigenic fragment thereof.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary.

(A) The nature of the invention;

(B) The breadth of the claims;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Nature of the invention: The instant claims are drawn to any vaccine to an unnamed pathogen comprising an immunogenic composition comprising exactly three different Bordetella antigens wherein the antigens are:

a) a Bordetella autotransporter protein consisting of polypeptide sharing at least 70% identity with SEQ ID NO:34 or antigenic fragment thereof;

b) a Bordetella adhesin consisting of FHA or antigenic fragment thereof;

c) a Bordetella toxin/invasion or antigens involved in toxin/invasion secretion consisting of pertussis toxin or antigenic fragment thereof.

Breadth of the claims: The claims encompass all vaccines, comprising an immunologically effective amount of a composition comprising exactly three different Bordetella antigens wherein the antigens are:

a) a Bordetella autotransporter protein consisting of polypeptide sharing at least *70% identity* with SEQ ID NO:34 or *antigenic fragment* thereof;

b) a Bordetella adhesin consisting of FHA or *antigenic fragment* thereof;

c) a Bordetella toxin/invasion or antigens involved in toxin/invasion secretion consisting of pertussis toxin or *antigenic fragment* thereof.

Guidance of the specification/The existence of working examples: The specification discloses immunized mice were challenged with K pertussis strain Tohama. There was no significant difference seen between the protection against *Bordetella. pertussis* offered by DTBrkA compared to control, indicating that immunization with BrkA alone is insufficient to elicit protection. The specification discloses in contrast, the addition of BrkA to a DTPa-2 vaccine produced a statistically significant increase in protection showing that, in combination with pertussis toxin (PT) and FHA, BrkA can produce additional protection. Furthermore the DTPa-3 BrkA vaccine provided excellent protection from challenge after 2 and 5 days but less protection after day 8 (see Example 12) (see pg. 103 and Figure 1). The specification discloses immunized mice were challenged with B. pertussis strain 18323. DTBrkA did not provide a significant protection over the control. BrkA in combination with other Bordetella pertussis antigens gives additional protection (see pgs. 103-104 and Figure 2). The challenged data as set forth supra does not demonstrate that the composition confers "protection" against infection. It merely shows that said composition reduces infection. Although the specification does disclose *in vivo* methods of determining the immune response in mice

challenges. The specification does not disclose any working example that any vaccine, comprising an immunogenic composition as set forth supra will work against a given infection. A vaccine by definition must provide protection against an infection demonstrable by challenge experiments. The specification is devoid of any teaching that the claimed vaccine discloses a protective response against any subject. Moreover, the instant claims encompass fragments of the recited proteins as well as proteins with at least 70% identity to SEQ ID NO:34. However, the specification is silent with regard to what specific immunoepitopes must be present in each antigen to elicit a protective immune response.

State of the art: Although many investigators have tried to develop vaccines based on specific antigens, it is well understood that the ability of an antigen to stimulate antibody production does not necessarily correlate with the ability of the antigen to stimulate an immune response capable of protecting an animal from infection (Chandrashekar et al., US Patent 6,248,329, col. 1, lines 35-41). It is well recognized in the vaccine art, that it is unclear whether an antigen derived from a pathogen will elicit protective immunity. Ellis (Chapter 29 of Vaccines, Plotkin, et al. (eds) WB Saunders, Philadelphia, 1998, especially p. 571, paragraph 2) exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies.., and thus protect the host against attack by the pathogen." Moreover, protein chemistry is probably one of the most unpredictable areas of biotechnology. Consequently, the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie et al (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome and form immunoepitopes. Bowie et al. further teach that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex.

(column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). For the reasons set forth supra, the state of the art is has limitations to a vaccine composition and the state of the art is unpredictable with regard any vaccine composition comprising a conjugate.

In conclusion, the claimed invention is not enabled for the vaccine comprising an immunogenic composition comprising a) a Bordetella autotransporter protein consisting of polypeptide sharing at least 70% identity with SEQ ID NO:34 or antigenic fragment thereof; b) a Bordetella adhesin consisting of FHA or antigenic fragment thereof; c) a Bordetella toxin/invasion or antigens involved in toxin/invasion secretion consisting of pertussis toxin or antigenic fragment thereof. The claims encompass all vaccines, comprising an immunogenic composition as set forth supra without disclosing what the vaccine will treat or prevent. The specification fails to teach that the immunogenic composition as set forth can produce a protective response in the host, as is requisite of a vaccine composition. The state of the art teaches that there are limitations to a vaccine composition and the state of the art is unpredictable. In view of the lack of support in the art and specification for an effective vaccine, it would require undue experimentation on the part of the skilled artisan to make and use the vaccine as claimed; therefore the claims are not enabled. As a result, for the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 11, 29-30, 32-33 36, and 53-54 rejected under 35 U.S.C. 103(a) as being unpatentable over Novotny et al US Patent No. 7,479,283 Date January 20, 2009 Date Filed May 25, 1995 in view of Oliver et al Vaccine 2002 Vol. 20 pgs. 235-241 as evidenced by Kinnear et al 2001 Infection and Immunity Vol. 69 No. 4 pgs. 1983-1993.

Claims 11, 29-30, 32-33 36, and 53-54 are immunogenic composition comprising three different Bordetella antigens wherein the antigens are:

a) a Bordetella autotransporter protein consisting of polypeptide sharing at least 70% identity with SEQ ID NO:34 or antigenic fragment thereof;

b) a Bordetella adhesin consisting of FHA or antigenic fragment thereof;

c) a Bordetella toxin/invasion or antigens involved in toxin/invasion secretion consisting of pertussis toxin or antigenic fragment thereof (claim 11).

Novotny et al teach an acellular pertussis vaccine comprising a combination of *Bordetella pertussis* antigens, said combination consisting of isolated and purified 69 kDa antigen of *Bordetella pertussis* and isolated and purified filamentous haemagglutinin (FHA) antigen of *Bordetella pertussis*, wherein the 69 kDa antigen and the filamentous haemagglutinin antigen are present in a ratio of from 1:1 to 1:10, wherein the vaccine is effective in inducing protection in a mammal to subsequent challenge by a virulent strain of *Bordetella pertussis* (see claim 1)

Novotny differs from the instant invention in that they don't explicitly disclose the use of BrkA protein (SEQ ID NO:34) in their vaccine composition.

Oliver et al teach polyclonal antibodies were raised to BrkA protein by using 1mg antigen per rabbit and 4 immunizations (see abstract pg. 236 column1 Section 2.3) (claims 11, 29, and 36) which correlate to an immunogenic composition comprising a) a Bordetella autotransporter protein consisting of polypeptide sharing at least 70% identity with SEQ ID NO:34 or antigenic fragment thereof . Oliver et al teach anti-BrkA antibodies were shown to boost the existing bactericidal mechanisms. Oliver et al teach the addition of anti-BrkA antiserum to human serum neutralizes complement resistance, thus indicating the possibility of preventing infection or colonization against Bordetella pertussis (see pg. 235 column last paragraph and pg. 240 column 1). Furthermore the antigens of Novotny et al et al teach an immunogenic composition comprising a polypeptide (pertusssis toxin) that is expressed during Bvg+early phase of Bordetella infection (see abstract) (claim 53); comprising a polypeptide (FHA) that is expressed during Bvg+late phase of Bordetella infection (see abstract) (claim 54) as evidenced by Kinnear et al .

According to MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose .... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to use SEQ ID NO: 34 , FHA, and pertussis toxin or any antigenic fragment thereof of each because these antigens are taught to be individually useful for that purpose.

Conclusion

10. Claims 11, 29-30, 32-33, 36, 53-54, and 65-66 are rejected and under examination.

Claims 1-10, 12-13, 23-28, 31, 34-35, 55-64, 70, and 72 are withdrawn.

Claim 14-22, 37-52, 67-68, and 71 are cancelled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi at 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina Archie
Examiner
Art Unit 1645

/Robert A. Zeman/
for Nina Archie, Examiner of Art Unit 1645